

FORM PTO-1390  
(REV 10-94)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

8279.829USWO

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)

Unknown

10/526858

INTERNATIONAL APPLICATION NO.

PCT/JP2003/011338

INTERNATIONAL FILING DATE

5 September 2003

PRIORITY DATE CLAIMED

6 September 2002

TITLE OF INVENTION

PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING MALIGNANT TUMOR AND UTILIZATION THEREOF  
(AS AMENDED HEREIN)

APPLICANT(S) FOR DO/EO/US

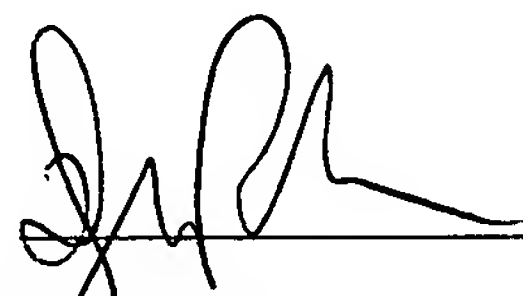
HIDAKA, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(I).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: Application Data Sheet, Communication Under 37 CFR 1.32(c)(3), International Publication Page, Form PCT/ISA/210, PCT Request, Form PCT/IB/304, Form PCT/IB/308, Form PCT/IB/332, Form PCT/IPEA/401, Form PCT/IPEA/408, Form PCT/IPEA/409

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEYS DOCKET NUMBER	
Unknown <b>10/526858</b>		PCT/JP2003/011338		8279.829USWO	
<b>BASIC NATIONAL FEE (37 CFR 1.492(a) (1)-(5)):</b>					
[X] a) Basic National fee.....\$300.00				\$300.00	
[X] b) Examination fee.....\$200.00				\$200.00	
[X] c) Search fee.....\$500.00				\$500.00	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$1000.00</b>	
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	Rate		
-100 =	/50 =		X \$250.00	\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	20 -20 =	0	X \$50.00	\$0.00	
Independent claims	1 -3 =	0	X \$200.00	\$0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$1000.00</b>	
Reduction by 1/2 for filing by small entity, if applicable. Small entity status is claimed pursuant to 37 CFR 1.27				\$	
<b>SUBTOTAL =</b>				<b>\$1000.00</b>	
Processing fee of \$130.00 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+ \$	
<b>TOTAL NATIONAL FEE =</b>				<b>\$1000.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+ \$40.00	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$1040.00</b>	
				Amount to be: refunded	\$
				charged	\$
<p>a. [X] Check(s) in the amount of <u>\$1000 and \$40</u> to cover the above fees is enclosed.</p> <p>b. [ ] Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>13-2725</u>.</p>					
<p><b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b></p>					
<p>SEND ALL CORRESPONDENCE TO: Douglas P. Mueller MERCHANT &amp; GOULD P.O. Box 2903 Minneapolis, MN 55402-0903</p>					
<p>SIGNATURE: </p> <p>NAME: Douglas P. Mueller</p> <p>REGISTRATION NUMBER: 30,300</p>					

S/N Unknown

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	HIDAKA, et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket No.:	08279.0829USWO
Title:	PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING MALIGNANT TUMOR AND UTILIZATION THEREOF		

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EV 495842177 US

Date of Deposit: March 2, 2005

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 

Name: David Ortiz

COMMUNICATION UNDER 37 C.F.R. §1.32(c)(3)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.32 (c)(3) please appoint the following practitioners named in the Power of Attorney to be recognized by the U.S. Patent Office as being of record in the above-identified application:

Brian H. Batzli (32,960)  
John A. Clifford (30,247)  
John J. Gresens (33,112)  
Curtis B. Hamre (29,165)  
Robert A. Kalinsky (50,471)

James A. Larson (40,443)  
Douglas P. Mueller (30,300)  
Joshua N. Randall (50,719)  
Michael D. Schumann (30,422)  
Gregory A. Sebald (33,280)

The undersigned was named on the Power of Attorney.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

Dated: March 2, 2005

By: 

Douglas P. Mueller  
Reg. No. 30,300

DPM/pjk

23552

PATENT TRADEMARK OFFICE

Applicant: HIDAKA, et al.  
 Docket: 8279.829USWO  
 Title: PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING MALIGNANT TUMOR AND UTILIZATION THEREOF

**CERTIFICATE UNDER 37 CFR 1.10:**

"Express Mail" mailing label number: EV 495842177 US

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By: 

Name: David Ortiz

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450

**23552**

PATENT TRADEMARK OFFICE

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.10.
- ☒ National Stage PCT Patent Application: Spec. 33 pgs; 23 claims; Abstract 1 pgs.  
The fee has been calculated as shown below in the 'Claims as Filed' table.
- ☒ 2 sheets of formal drawings
- ☒ A signed Combined Declaration and Power of Attorney
- ☒ Assignment of the invention to D. Western Therapeutics Institute and NIPPON SHINYAKU CO., LTD.,  
Recordation Form Cover Sheet
- ☒ A check in the amount of \$1000.00 to cover the Filing Fee
- ☒ A check for \$40.00 to cover the Assignment Recording Fee.
- ☒ Application Data Sheet, 4 pages.
- ☒ Other: Form PTO-1390, Preliminary Amendment, Communication Under 37 CFR 1.32(c)(3), International Publication Page, Form PCT/ISA/210, PCT Request, Form PCT/IB/304, Form PCT/IB/308, Form PCT/IB/332, Form PCT/IPEA/401, Form PCT/IPEA/408, Form PCT/IPEA/409
- ☒ Return postcard

**CLAIMS AS FILED**

Number of Claims Filed	No.	In Excess of	Extra	Rate	Fee
Total Claims	20	20	0	50	= 0.00
Independent Claims	1	3	0	200	= 0.00
Multiple Dependent Claims Fee					= 0
Basic Filing Fee					= 300.00
Search Fee					= 500.00
Examination Fee					= 200.00
Utility Application Size Fee		100			= 0
Total					= 1000.00

Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

Merchant & Gould P.C.  
 P.O. Box 2903 Minneapolis, MN 55402-0903  
 612.332.5300

By: 

Name: Douglas P. Mueller  
 Reg. No.: 30,300  
 Initials: DPM/pjk

(PTO TRANSMITTAL - NEW FILING)